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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

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First Named Inventor or Application Identifier	Thomas P. Stewart et al.		
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APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

1. ■ Fee Transmittal Form
(Submit an original, and a duplicate for fee processing)

2. ■ Specification [*Total Pages* / 28 /]
(preferred arrangement set forth below)
- Descriptive title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R&D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings *(if filed)*
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3. ■ Drawing(s) *(35 USC 113)* [*Total Sheets* / 5 /]

4. ■ Oath or Declaration [*Total Pages* / 3 /]
a. ■ Newly executed (original or copy)
b. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 17 completed)
[Note Box 5 below]
i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).

5. ☐ Incorporation By Reference *(useable if Box 4b is checked)*
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Microfiche Computer Program *(Appendix)*

7. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
a. ☐ Computer Readable Copy
b. ☐ Paper Copy (identical to computer copy)
c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8 ■ Assignment Papers (cover sheet & document(s))

9. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney
(when there is an assignee)

10. ☐ English Translation Document *(if applicable)*

11. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations

12. ☐ Preliminary Amendment

13. ■ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)

14. ■ Small Entity ☐ Statement filed in prior application, Statement(s) Status still proper and desired

15. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)

16. ■ Other: checks - $1035.00 and 40.00

17. **If a CONTINUING APPLICATION,** *check appropriate box and supply the requisite information:*
☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of the prior application No: __ /_____

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Name

Kathleen M. Ashton
Signature

STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(c)) - SMALL BUSINESS CONCERN	Docket Number 01978.0229

Applicant or Patentee: Thomas P. Stewart and Hermann K. Pohl
Application or Patent No.:
Filed or Issued: June 26, 2000
Title: AUTOMATIC PATIENT CONTROL DEVICE

I hereby declare that I am

/_/ the owner of the small business concern identified below:
/X/ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN Gaymar Industries, Inc.
ADDRESS OF SMALL BUSINESS CONCERN 10 Centre Drive
Orchard Park, New York 14127

I hereby state that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR Part 121 for purposes of paying reduced fees to the United States Patent and Trademark Office. Questions related to size standards for a small business concern may be directed to: Small Business Administration, Size Standards Staff, 409 Third Street, SW, Washington, DC 20416.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

/X/ the specification filed herewith with title as listed above.
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If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights in the invention must file separate statements as to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

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NAME OF PERSON SIGNING Thomas P. Stewart

TITLE OF PERSON OTHER THAN OWNER President and Chief Operating Officer

ADDRESS OF PERSON SIGNING Gaymar Industries, Inc., 10 Centre Drive, Orchard Park, New York 14127

SIGNATURE Thomas P. Stewart Date 6/22/2000

Automatic Patient Control Device

Field of the Invention

The present invention relates to an automatic patient control device that delivers a medium to a patient.

Background of the Invention

Gaymar Industries, Inc. (the assignee of the present invention) is the owner and manufacturer of the MEDI-THERM II® hypo/hyperthermia machine. This machine delivers water to a blanket (*i.e.*, Gaymar's Hypo/hyper thermia blanket, Gaymar's THERMACARE® blanket or Gaymar's MEDI-TEMP® blanket), a mattress pad (*i.e.*, Gaymar's Alternating Pressure Pad (model no. EFF302)), a chair pad, or a mattress unit (*i.e.*, Gaymar's CLINIDYNE® mattress)(collectively the blankets, pads, and mattresses and obvious variations thereof are hereinafter "Objects"). In particular, the Objects surround a patient or applied to predetermined portions of the patient.

The object of the MEDI-THERM II® hypo/hyperthermia machine is to stabilize a patient who is experiencing hypothermia or hyperthermia or, in some instances, to actively cause hypothermia or hypothermia as therapy. To understand the MEDI-THERM II® device, we will revert to Figure 1 (prior art) which is a flow diagram of how the MEDI-THERM II® device distributes water to and from an Object. The liquid medium enters MEDI-THERM II® device through return inlet 52. From return inlet 52, the liquid medium traverses through a first conduit 30 to a first solenoid valve 32 for cold liquid medium or a second solenoid valve 34 for warm liquid medium.

From the first solenoid valve 32, the liquid medium goes through a second conduit 36 and a first cold inlet 37 to a cold reservoir 38. The cold reservoir 38 is a conventional cooling unit that cools the water, *i.e.*, a refrigeration system's or air conditioner's evaporator. The evaporator in the reservoir maintains a large quality of water at a predetermined temperature - normally 4°C - (hereinafter "Cold Water"). Water entering the reservoir is cooled by mixing with the Cold Water already in the reservoir (hereinafter "Reservoir Water".) If the cold reservoir 38 overflows, the Cold Water escapes from the device 10 through an overflow outlet 40. The Cold Water then flows through a cold outlet 41 of the cold reservoir 38 and a third conduit 42 to a manifold 44.

Similarly from the second solenoid 34, the water goes to a hot reservoir 46 through a fourth conduit 48 and a hot inlet port 49. The hot reservoir 46 is a conventional heating apparatus that heats the liquid medium (hereinafter "Warm Water"). The Warm Water flows through the warm outlet 56 to the manifold 44.

At the manifold 44 the Warm Water and the Cold Water converge. The selection of which return water path is active and its length of time active is controlled via solenoid valves 32 and 34 to attain a desired temperature (hereinafter "Mixed Water"). The Mixed Water is drawn through a sixth conduit 74 by a conventional pump 76, to supply outlet 14. A flow switch 78 on the sixth conduit 74 senses whether the Mixed Water reaches the supply outlet 14. Obviously, when the flow switch 78 is on, the Mixed Water reaches the supply outlet 14. And when the flow switch 78 is off, the Mixed Water fails to reach the supply outlet

14. A seventh conduit 80 connects with the first conduit 30 to provide quelling of temperature overshoot when no Object is connected.

When the Mixed Water reaches the supply outlet 14, the Mixed Water is released into the outlet conduit 18 into the Object 16. The Mixed Water traverses through the Object 16 to the return conduit 50 and into the return inlet 52.

The Mixed Water temperature is altered with the first solenoid valve 32 which controls the Warm Water and the second solenoid valve 34 which controls the Cold Water. The amount of water each valve 32, 34 allows into the manifold 44 depends on the temperature of the mammal 20 and the temperature of the Mixed Water in the Object.

The temperature of the mammal 20 is measured by a first conventional temperature sensing device (i.e. thermistors or thermocouples) 130 connected to a preselected portion of the mammal 20 and interconnected to a processing unit 90. The measurement from the first temperature sensing device 130 is transmitted to a processing unit 90.

The temperature of the Mixed Water in the Object is measured by a second conventional temperature measuring device 132 placed in the Object 16, in the supply conduit 18, the supply outlet 14, the sixth conduit 74, or manifold 44. The measurement from the second temperature measuring device 132 is transmitted to the processing unit 90.

The processing unit 90 compares the measurement from the first temperature sensing device 130 (hereinafter "First Measurement") to the Set Point Body temperature of the mammal 20 (hereinafter "Set Point

Body Temperature"). The processing unit 90 determines whether First Measurement is above or below the Set Point Body Temperature.

Initially when the First Measurement is above the Set Point Body Temperature, the MEDI-THERM II® device, by design, applies the coldest water available (normally 4°C) to the Object 16. Figure 2 (prior art) illustrates this design feature in section 200 wherein the temperature of the First Measurement is represented as line 201, the Set Point Body Temperature is represented as line 202, and the Mixed Water is represented as line 203. Once the First Measurement 201 falls below the Set Point Body Temperature 203, the processing unit uses the solenoid valves 32, 34 to alter the temperature of the Mixed Water, not at a predetermined differential from the First Measurement, to eventually stabilize the patient to the Set Point Body Temperature. See section 204 of Figure 2.

Likewise, when the First Measurement is below the Set Point Body Temperature, the MEDI-THERM II® device, by design, applies the warmest water available (normally 42°C) to the Object 16. Once the First Measurement 201 falls above the Set Point Body Temperature 203, the processing unit uses the solenoid valves 32, 34 to alter the temperature of the Mixed Water, not at a predetermined differential from the First Measurement, to eventually stabilize the patient to the Set Point Body Temperature. See section 204 of Figure 2.

The MEDI-THERM II® device, however, can sometimes cause discomfort to the patient. This discomfort can occur when the MEDI-THERM II® device applies the coldest water available (normally 4°C) or the warmest water available (normally 42°C) into the Object during the

initial time frame, shown in section 200 of Figure 2, or when the First Measurement and the Set Point Body Temperature difference is not-so-great but exists for a long time. When the patient is exposed to the coldest or warmest water available, the patient may experience some discomfort.

The present invention solves this problem.

Brief Description of the Drawings

Figure 1 illustrates a prior art schematic flow diagram of how the MEDI-THERM II® hypo/hyperthermia machine distributes water to and from an Object.

Figure 2 illustrates a prior art graph of the Figure 1.

Figure 3 illustrates the exterior embodiment of the present invention.

Figure 4 illustrates a schematic flow diagram of how the present invention distributes a liquid medium to and from an Object

Figures 5A, 5B, and 5C illustrate graphs showing the actual temperature of a patient and the temperature of the desired medium applied to the patient over time of the present invention.

Figure 6 illustrates an alternative embodiment of Figure 4.

Summary of the Present Invention

The present invention relates to regulating the temperature of a desired medium that is applied to the exterior surface of a mammal. These devices have been used in the past but not with the ability to control the temperature of the desired medium in a predetermined ratio to the temperature of the mammal. With such

control, the present invention decreases the chance of discomforting the patient when the patient's temperature is being brought to a Set Point Body temperature.

Detailed Description of the Present Invention

One embodiment of the present invention is illustrated in Figure 3. This embodiment relates to a liquid medium delivery device 10. The exterior of the device 10 has at least one supply outlet 14, a kill switch 444 which can shut down the entire device 10 by conventional interconnections between the various components of device 10, a display/input unit 46, at least one outlet conduit 18, a return conduit 50, a return inlet 52, and an Object 16.

Figure 4 is a flow diagram of how device 10 distributes the liquid medium. The liquid medium enters device 10 through the return inlet 52. From return inlet 52, the liquid medium traverses through the first conduit 30 to the first solenoid valve 32 for a cold liquid medium or the second solenoid valve 34 for a warm liquid medium.

From the first solenoid 32 which is controlled by a processor unit 90 (to be described later), the liquid medium goes through a second conduit 36 and the first cold inlet 37 of the cold reservoir 38 to the cold reservoir 38. The cold reservoir 38 is a conventional cooling unit that cools a liquid, *i.e.*, a refrigeration system's evaporation or an air conditioner's evaporator. The evaporator in the reservoir maintains a large quantity of fluid at a predetermined temperature normally 4°C (hereinafter "Cold Medium"). Liquid medium entering the reservoir is cooled by mixing with the liquid medium already within the reservoir. If the cold

reservoir 38 overflows, the liquid medium escapes from the device 10 through the overflow outlet 40. The Cold Medium then flows through the cold outlet 41 of the cold reservoir 38 and the third conduit 42 to a manifold 44.

Similarly from the second solenoid 34 which is controlled by the processor unit 90, the liquid medium goes to a hot reservoir 46 through the fourth conduit 48 and the hot inlet port 49 of the hot reservoir 46. The hot reservoir 46 is a conventional heating apparatus that heats the liquid medium (hereinafter "Warm Medium"). The warm Medium flows through the warm outlet 56 of the hot reservoir 46 to the manifold 44.

At the manifold 44, the Warm Medium and the Cold Medium converge. The selection of which liquid medium path is active and its length of time active is controlled via solenoid valves 32 and 34 to attain a desired temperature. The Mixed Medium is drawn through the sixth conduit 74 by the conventional pump 76, to supply outlet 14. A flow switch 78 on the sixth conduit 74 senses whether the Mixed Medium reaches the supply outlet 14. Obviously, when the flow switch 78 is on, the Mixed Medium reaches the supply outlet 14. And when the flow switch 78 is off, the Mixed Medium fails to reach the supply outlet 14. A seventh conduit 80 connects with the first conduit 30, to provide quelling of temperature overshoot when no Object is connected.

When the Mixed Medium reaches the supply outlet 14, the liquid medium is released into the outlet conduit 18 into the Object 16. The Mixed Medium traverses through the Object 16 to the return conduit 50 and into the return inlet 52. And the process is repeated.

The Mixed Medium temperature is altered by the first solenoid valve 32 which controls the intake of the

Warm Medium and the second solenoid valve 34 which controls the intake of the Cold Medium. The amount of medium each solenoid valve 32, 34 allows into the manifold 44 depends on the temperature of the mammal 20 and, sometimes depending on the embodiment of the present invention, the temperature of the Mixed Medium in the Object.

The temperature of the mammal 20 is measured by the first conventional temperature sensing device 130 connected to the preselected portion of the mammal 20 and interconnected to the processing unit 90. The measurement from the first temperature sensing device 130 is transmitted to the processing unit 90.

The temperature of the Mixed medium in the Object is measured by the second conventional temperature measuring device 132 placed in the Object, in the supply conduit 18, the supply outlet 14, the manifold 44, or the sixth conduit 74. The measurement from the second temperature measuring device 132 is transmitted to the processing unit 90.

Initially, the processing unit 90 compares the measurement from the first temperature sensing device 130 (hereinafter "First Measurement") to the Set Point Body temperature of the mammal 20 (hereinafter "Set Point Body Temperature"). The processing unit 90 determines the differential and, in return, adjusts the temperature of the Mixed Medium to a preset differential by controlling the solenoid valves 32, 34.

When the First Measurement is above the Set Point Body Temperature, the processing unit 90 controls the first and second solenoid valves 32, 34 to alter the temperature of the Mixed Medium to a predetermined differential from the First Measurement. The

predetermined differential ranges from 0.1 to 35 degrees Celsius, and preferably ranges from 5 to 15 degrees Celsius, below the First Measurement.

Initially when the First Measurement is above the Set Point Body Temperature, the device 10 applies, by the processing unit 90 controlling the first and second solenoids 32, 34, a Mixed Medium into the Object 16 having a predetermined differential from the First Measurement. The predetermined differential ranges from 0.1 to 35 degrees Celsius, and preferably ranges from 5 to 15 degrees Celsius, below the First Measurement. Figures 5a (a 10°C differential) and 5b (a 15°C differential) illustrate this design feature in section 400 wherein the temperature of the First Measurement is represented as line 401, the Set Point Body Measurement is represented as line 402, and the Mixed Medium is represented as line 403 at different differentials. Once the First Measurement 401 falls below the Set Point Body Temperature 402, the first and second solenoid valves 32, 34 alter the temperature of the Mixed Medium, to eventually stabilize the patient to the Set Point Body Temperature. See section 404 of Figures 5A and B.

Likewise, when the First Measurement is initially below the Set Point Body Temperature, the processing unit 90 controls the first and second solenoid valves 32, 34 to alter the temperature of the Mixed Medium to a pre-set differential from the First Measurement. The pre-set differential ranges from 0.1 to 35 degrees Celsius, and preferably ranges from 5 to 15 degrees Celsius, above the actual temperature, so long as the processing unit 90 does not alter the temperature of the Mixed Medium above a predetermined-maximum temperature. The predetermined-maximum temperature is 0.1 to 10

degrees Celsius, and preferably about 5 degrees Celsius, above the normal temperature of the mammal.

And when the First Measurement is about the Set Point Body Temperature, the processing unit 90 controls the first and second valves 32, 34 to alter the temperature of the Mixed Medium to a temperature which will maintain the First Measurement about the Set Point Body temperature.

The liquid medium can be any liquid that transfers thermal energy to a mammal 20 and wherein the liquid can be readily altered to a Warm Medium or a Cold Medium, like water or water-based solutions.

Alternatively, the liquid medium set forth in the present invention can be substituted by a gaseous medium, like air. When device 10 delivers air instead of a liquid medium, device 10 is altered. Instead of having valves 32, 34, conduits 48, 36, 42, and reservoirs 38, 46, the device 10 has a different temperature and intake system.

Turning to Figure 6, the air is drawn into device 10 through the inlet 52 by a conventional fan 540. From the inlet 52, the air medium traverses through a ninth conduit 302 to a plenum 304. The plenum 304 has a cooling unit 306, like an air conditioner, and a heating unit 308, like a heat pump. The processing unit 90 controls the cooling unit 306 and the heating unit 308 by conventional methods well known to those skilled in the art.

The air then escapes into the manifold 44 and follows route set forth for Figure 3, except the air does not return to the device 10 from the Object 16. The temperature of the Mixed Medium in the Object 16 is measured by the second conventional temperature

measuring device 132 placed in the Object 16, in the supply conduit 18, the supply outlet 14, the sixth conduit 74, the manifold 44 or the plenum 304. The measurement from the second temperature measuring device is transmitted to the processing unit 90.

The processing unit 90, in return, alters the operation of the cooling unit 306 and the heating unit 308 to obtain the desired air temperature.

In one embodiment of the present invention, the values for the predetermined differential, the pre-set differential, the predetermined-maximum temperature, the Set Point Body Temperature, and the pre-selected differential can be entered into the processing unit 90 through the display/input unit 46 by a user. Alternatively, these values can be pre-programmed and activated by merely striking a desired switch. Device 10 when using these values decrease the discomfortness to the patient 20.

Alternatively, the processing unit 90 can be programmed and/or pre-set to alter the temperature of the Mixed Medium and/or the temperature of the mammal 20 at a set rate. For example, altering the temperature of the Mixed Medium or mammal 16 at 2°C, or any other temperature change, per hour. These changes can occur in time increments, as well. For example, the processing unit 90 can be programmed, as illustrated in Figure 5c wherein the lines 401 and 403 are defined above, to (1) cool the mammal 16 (or Mixed Medium) to 34°C at 2°C/hour during a first time period (area 600), (2) cool the mammal 16 (or Mixed Medium) to 32°C using a 20°C maximum differential during a second time period (area 601), (3) during a third time frame, the mammal's (or Mixed Medium's) temperature is to be maintained at

32°C - to maintain this temperature for the mammal the Mixed Medium is at a maximum pre-set differential, *i.e.*, a 10°C maximum differential from the mammal's temperature - for 1 hour (area 602); and (4) raise the mammals' (or Mixed Medium's) temperature to 37°C, or any other predetermined temperature at a rate of 4°C per hour (area 603). Obviously, these examples can be used with different temperatures, different differentials, and different, desired rates. By controlling these rates, temperatures, and differentials individually and/or collectively, by manual means of inputting the data into the processing unit 90, automatic means of a pre-programmed rate and/or temperature, or a combination of both means, the processing unit 90 controls the solenoid valves 32,34, 320 and manifold 44 to distribute the Mixed Medium at the predetermined temperature and/or predetermined rate.

While preferred embodiments of the present invention have been disclosed, it will be appreciated that it is not limited thereto but may be otherwise embodied with the scope of the following claims.

We claim the following:

1. A device for delivering a desired medium at certain temperature ranges for temperature management of a mammal, comprising:

an inlet source receives the desired medium and directs the desired medium to a temperature-control device;

a bio-feedback device measures the mammal's actual temperature, and transmits the measurement to the temperature-control device;

depending on the measurement, the temperature-control device alters the temperature of the desired medium; and

an outlet source directs the desired medium to manage the temperature of the mammal;

wherein the mammal is to have its temperature set to a predetermined-desired temperature which is entered into the temperature-control device;

wherein when the actual temperature is above the predetermined-desired temperature, the temperature-control device alters the temperature of the desired medium to a predetermined differential from the actual temperature; and

wherein when the actual temperature is below the predetermined-desired temperature, the temperature-control device alters the temperature of the desired medium to a pre-set differential from the actual temperature.

2. The device of claim 1 wherein the desired medium is water.

3. The device of claim 1 wherein the desired medium is air.

4. The device of claim 1 wherein the predetermined differential ranges from 0.1 to 35 degrees Celsius below the actual temperature.

5. The device of claim 1 wherein the predetermined differential ranges from 5 to 15 degrees Celsius below the actual temperature.

6. The device of claim 1 wherein the pre-set differential ranges from 0.1 to 35 degrees Celsius above the actual temperature, so long as the temperature-control device does not alter the temperature of the desired medium above a predetermined-maximum temperature.

7. The device of claim 1 wherein the pre-set differential ranges from 5 to 15 degrees Celsius above the actual temperature.

8. The device of claim 6 wherein the predetermined-maximum temperature is 0.1 to 10 degrees Celsius above a predetermined-healthy temperature of the mammal.

9. The device of claim 6 wherein the predetermined-maximum temperature is about 5 degrees Celsius above a predetermined-healthy temperature of the mammal.

10. A device for delivering a desired medium within a desired temperature range for temperature management of a mammal, comprising:

an inlet source receives the desired medium and directs the desired medium to a temperature-control device;

a bio-feedback device measures the mammal's actual temperature, and transmits the measurement to the temperature-control device;

depending on the measurement, the temperature-control device alters the temperature of the desired medium; and

an outlet source directs the desired medium to manage the temperature of the mammal;

wherein the mammal has a predetermined-healthy temperature which is entered into the temperature-control device;

wherein when the actual temperature is above the predetermined-healthy temperature, the temperature-control device alters the temperature of the desired medium to a predetermined differential from the actual temperature;

wherein when the actual temperature is below the predetermined-healthy temperature, the temperature-control device alters the temperature of the desired medium to a pre-set differential from the actual temperature; and

wherein when the actual temperature is about the predetermined-healthy temperature, the temperature-control device alters the temperature of the desired medium to maintain the actual temperature.

11. The device of claim 10 wherein the desired medium is water.

12. The device of claim 10 wherein the desired medium is air.

13. The device of claim 10 wherein the predetermined differential ranges from 0.1 to 35 degrees Celsius below the actual temperature.

14. The device of claim 10 wherein the predetermined differential ranges from 5 to 15 degrees Celsius below the actual temperature.

15. The device of claim 10 wherein the pre-set differential ranges from 0.1 to 35 degrees Celsius above the actual temperature, so long as the temperature-control device does not alter the temperature of the desired medium above a predetermined-maximum temperature.

16. The device of claim 10 wherein the pre-set differential ranges from 5 to 15 degrees Celsius above the actual temperature.

17. The device of claim 15 wherein the predetermined-maximum temperature is 0.1 to 10 degrees Celsius above the predetermined-healthy temperature.

18. The device of claim 15 wherein the predetermined-maximum temperature is about 5 degrees Celsius above the predetermined-healthy temperature.

19. The device of claim 10 wherein the pre-selected differential is from 0.01 to 5 degrees Celsius above and below the predetermined-healthy temperature.

20. The device of claim 1 wherein the temperature-control device is a heat transfer unit with a temperature-measurement instrument.

21. The device of claim 10 wherein the temperature-control device is a heat transfer unit with a temperature-measurement instrument.

22. The device of claim 1 wherein the outlet source directs the desired medium into a blanket.

23. The device of claim 10 wherein the outlet source directs the desired medium into a blanket.

24. The device of claim 22 wherein the blanket has a plurality of channels.

25. The device of claim 23 wherein the blanket has a plurality of channels.

26. The device of claim 22 wherein the blanket has a plurality of apertures directing the desired medium in the direction of the mammal.

27. The device of claim 23 wherein the blanket has a plurality of apertures directing the desired medium in the direction of the mammal.

28. The device of claim 1 wherein the outlet source directs the desired medium under a blanket.

29. The device of claim 10 wherein the outlet source directs the desired medium under a blanket.

30. A method of using a device for delivering a desired medium within a selected temperature range for temperature management of a mammal, comprising following steps:

directing the desired medium into an inlet source and a temperature-control device;

measuring the mammal's actual temperature with a bio-feedback device, and transmitting the measurement to the temperature-control device;

depending on the measurement, altering the temperature of the desired medium with the temperature-control device;

directing the desired medium through an outlet source to manage the temperature of the mammal;

wherein the mammal is to have its temperature adjusted to a predetermined-desired temperature which is entered into the temperature-control device;

wherein when the actual temperature is above the predetermined-desired temperature, the temperature-control device alters the temperature of the desired medium to a predetermined differential from the actual temperature; and

wherein when the actual temperature is below the predetermined-desired temperature, the temperature-control device alters the temperature of the desired medium to a pre-set differential from the actual temperature.

31. The method of claim 30 wherein the desired medium is water.

32. The method of claim 30 wherein the desired medium is air.

33. The method of claim 30 wherein the predetermined differential ranges from 0.1 to 35 degrees Celsius below the actual temperature.

34. The method of claim 30 wherein the predetermined differential ranges from 5 to 15 degrees Celsius below the actual temperature.

35. The method of claim 30 wherein the pre-set differential ranges from 0.1 to 35 degrees Celsius above the actual temperature, so long as the temperature-control device does not alter the temperature of the desired medium above a predetermined-maximum temperature.

36. The method of claim 30 wherein the pre-set differential ranges from 5 to 15 degrees Celsius above the actual temperature.

37. The method of claim 35 wherein the predetermined-maximum temperature is 0.1 to 10 degrees Celsius above a predetermined-healthy temperature of the mammal.

38. The method of claim 35 wherein the predetermined-maximum temperature is about 5 degrees

Celsius above a predetermined-healthy temperature of the mammal.

39. The method of claim 30 wherein the pre-selected differential is from 0.01 to 5 degrees Celsius above and below the predetermined-healthy temperature.

40. The method of claim 30 wherein the temperature-control device is a heat transfer unit with a temperature-measurement instrument.

41. The method of claim 30 wherein the outlet source directs the desired medium into a blanket.

42. The method of claim 41 wherein the blanket has a plurality of channels.

43. The method of claim 41 wherein the blanket has a plurality of apertures directing the desired medium in the direction of the mammal.

44. The method of claim 30 wherein the outlet source directs the desired medium under a blanket.

45. The device of claim 10 wherein the outlet source directs the desired medium to a mattress.

46. The device of claim 1 wherein the outlet source directs the desired medium to a mattress.

47. The method of claim 30 wherein the outlet source directs the desired medium to a mattress.

48. The device of claim 10 wherein the outlet source directs the desired medium to a mattress pad.

49. The device of claim 1 wherein the outlet source directs the desired medium to a mattress pad.

50. The method of claim 30 wherein the outlet source directs the desired medium to a mattress pad.

51. The device of claim 1 wherein the temperature-control device can alter the temperature of the desired medium at a predetermined rate.

52. The device of claim 10 wherein the temperature-control device can alter the temperature of the desired medium at a predetermined rate.

53. The method of claim 30 wherein the temperature-control device can alter the temperature of the desired medium at a predetermined rate.

54. A device for delivering a desired medium at certain temperature ranges for temperature management of a mammal, comprising:

an inlet source receives the desired medium and directs the desired medium to a temperature-control device;

a bio-feedback device measures the mammal's actual temperature, and transmits the measurement to the temperature-control device;

depending on the measurement, the temperature-control device alters the temperature of the desired medium; and

an outlet source directs the desired medium to manage the temperature of the mammal;

wherein the mammal is to have its temperature set to a predetermined-desired temperature which is entered into the temperature-control device;

wherein when the actual temperature is above the predetermined-desired temperature, the temperature-control device alters the temperature of the desired medium at a predetermined rate; and

wherein when the actual temperature is below the predetermined-desired temperature, the temperature-control device alters the temperature of the desired medium at a predetermined rate.

55. The device of claim 54 wherein the desired medium is water.

56. The device of claim 54 wherein the desired medium is air.

57. The device of claim 54 wherein the predetermined differential ranges from 0.1 to 35 degrees Celsius below the actual temperature.

58. The device of claim 54 wherein the predetermined differential ranges from 5 to 15 degrees Celsius below the actual temperature.

59. The device of claim 54 wherein the pre-set differential ranges from 0.1 to 35 degrees Celsius above the actual temperature, so long as the temperature-control device does not alter the temperature of the

desired medium above a predetermined-maximum temperature.

60. The device of claim 54 wherein the pre-set differential ranges from 5 to 15 degrees Celsius above the actual temperature.

61. The device of claim 59 wherein the predetermined-maximum temperature is 0.1 to 10 degrees Celsius above a predetermined-healthy temperature of the mammal.

62. The device of claim 59 wherein the predetermined-maximum temperature is about 5 degrees Celsius above a predetermined-healthy temperature of the mammal.

63. The device of claim 54 wherein the temperature-control device alters the temperature of the desired medium to a pre-set differential from the actual temperature.

64. A device for delivering a desired medium at certain temperature ranges for temperature management of a mammal, comprising:

an inlet source receives the desired medium and directs the desired medium to a temperature-control device;

a bio-feedback device measures the mammal's actual temperature, and transmits the measurement to the temperature-control device;

depending on the measurement, the temperature-control device alters the temperature of the desired medium; and

an outlet source directs the desired medium to manage the temperature of the mammal;

wherein the mammal is to have its temperature set to a predetermined-desired temperature which is entered into the temperature-control device;

wherein when the actual temperature is above the predetermined-desired temperature, the temperature-control device alters the temperature of the mammal at a predetermined rate; and

wherein when the actual temperature is below the predetermined-desired temperature, the temperature-control device alters the temperature of the mammal at a predetermined rate.

65. The device of claim 64 wherein the desired medium is water.

66. The device of claim 64 wherein the desired medium is air.

67. The device of claim 64 wherein the predetermined rate ranges from 0.1 to 25 degrees Celsius per hour.

68. The device of claim 64 wherein the predetermined rate ranges from 1 to 15 degrees Celsius per hour.

69. The device of claim 64 wherein the temperature-control device is a heat transfer unit with a temperature-measurement instrument.

70. The device of claim 64 wherein the outlet source directs the desired medium into a blanket.

71. The device of claim 69 wherein the predetermined-maximum temperature is 0.1 to 10 degrees Celsius above a predetermined-healthy temperature of the mammal.

72. The device of claim 69 wherein the predetermined-maximum temperature is about 5 degrees Celsius above a predetermined-healthy temperature of the mammal.

73. The device of claim 64 wherein the temperature-control device alters the temperature of the desired medium to a pre-set differential from the actual temperature.

74. The device of claim 1 wherein the predetermined-desired temperature is selected from the group consisting of a temperature below the mammal's normal temperature, the mammal's normal temperature, and a temperature above the mammal's normal temperature.

75. The device of claim 64 wherein the predetermined-desired temperature is selected from the group consisting of a temperature below the mammal's normal temperature, the mammal's normal temperature, and a temperature above the mammal's normal temperature.

76. The method of claim 30 wherein the predetermined-desired temperature is selected from the group consisting of a temperature below the mammal's normal temperature, the mammal's normal temperature, and a temperature above the mammal's normal temperature.

77. The device of claim 64 wherein the blanket has a plurality of channels.

78. The device of claim 64 wherein the blanket has a plurality of apertures directing the desired medium in the direction of the mammal.

79. The device of claim 64 wherein the outlet source directs the desired medium under a blanket.

80. The device of claim 64 wherein the outlet source directs the desired medium to a mattress.

81. The device of claim 64 wherein the outlet source directs the desired medium to a mattress pad.

82. The device of claim 54 wherein the blanket has a plurality of channels.

83. The device of claim 54 wherein the blanket has a plurality of apertures directing the desired medium in the direction of the mammal.

84. The device of claim 54 wherein the outlet source directs the desired medium under a blanket.

85. The device of claim 54 wherein the outlet source directs the desired medium to a mattress.

86. The device of claim 54 wherein the outlet source directs the desired medium to a mattress pad.

87. The device of claim 54 wherein the temperature-control device is a heat transfer unit with a temperature-measurement instrument.

88. The device of claim 54 wherein the outlet source directs the desired medium into a blanket.

Abstract

The present invention relates to regulating the temperature of a desired medium that is applied to the exterior surface of a mammal. These devices have been used in the past but not with the ability to control the temperature of the desired medium in a predetermined ratio to the temperature of the mammal. With such control, the present invention decreases the change of discomforting the patient when the patient's temperature is being brought to a set point temperature body temperature.

Figure 1

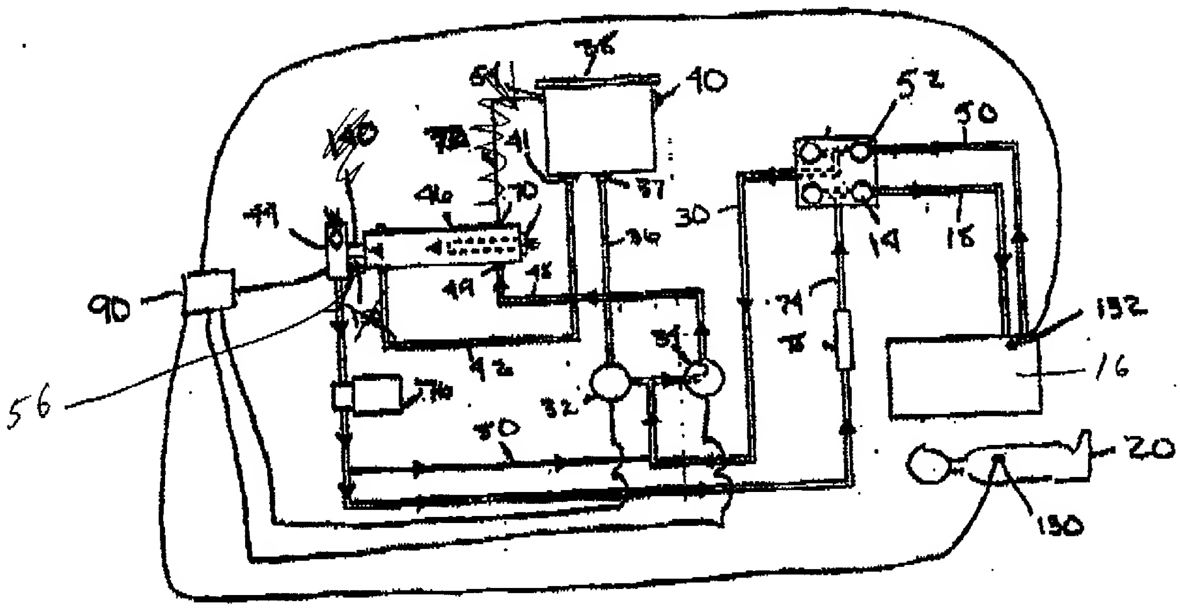
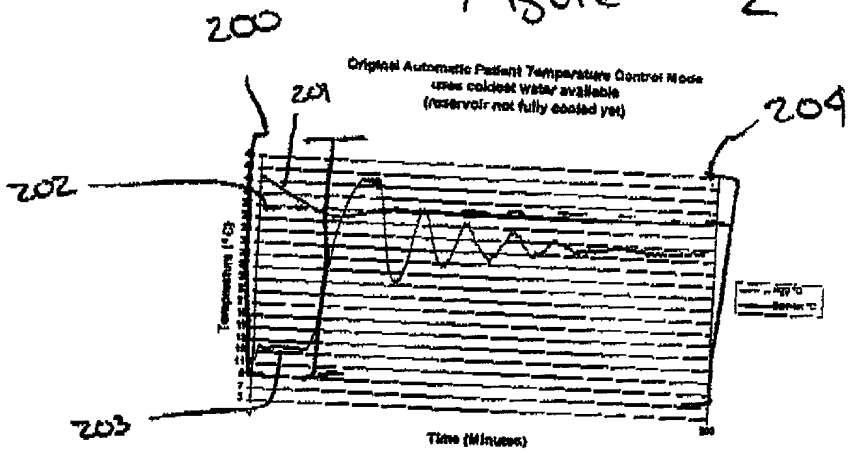


Figure 2



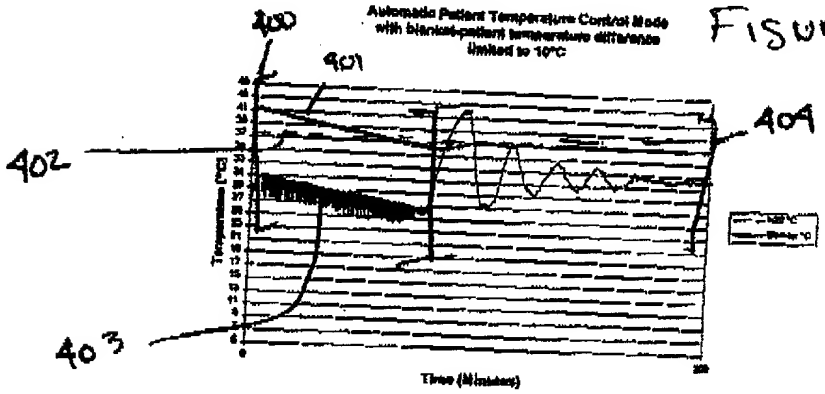


Figure 5A

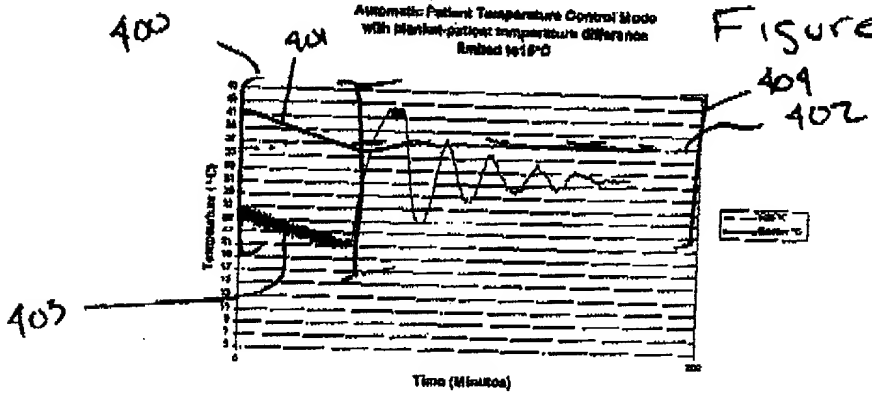
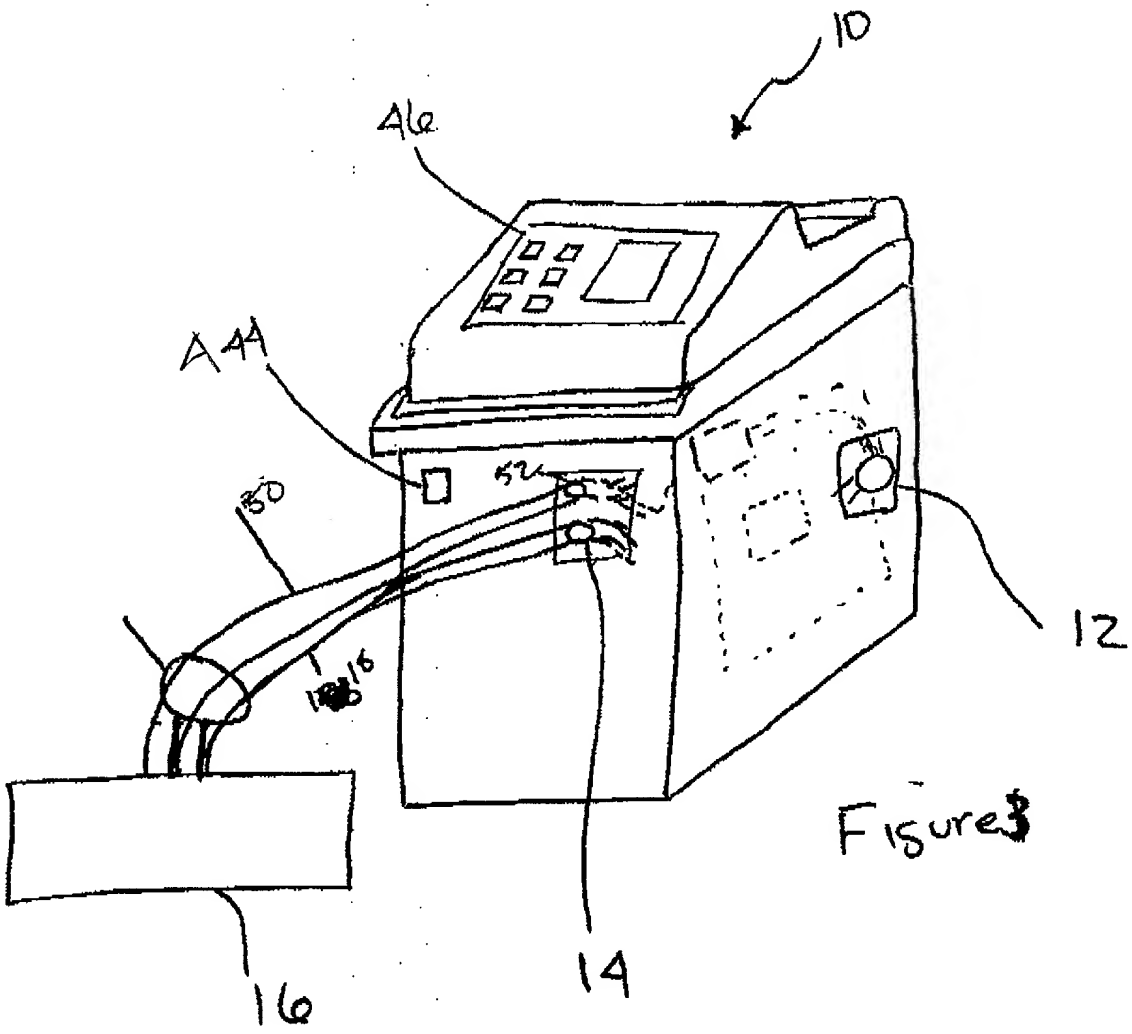


Figure 5B



Fisure3

Figure 4

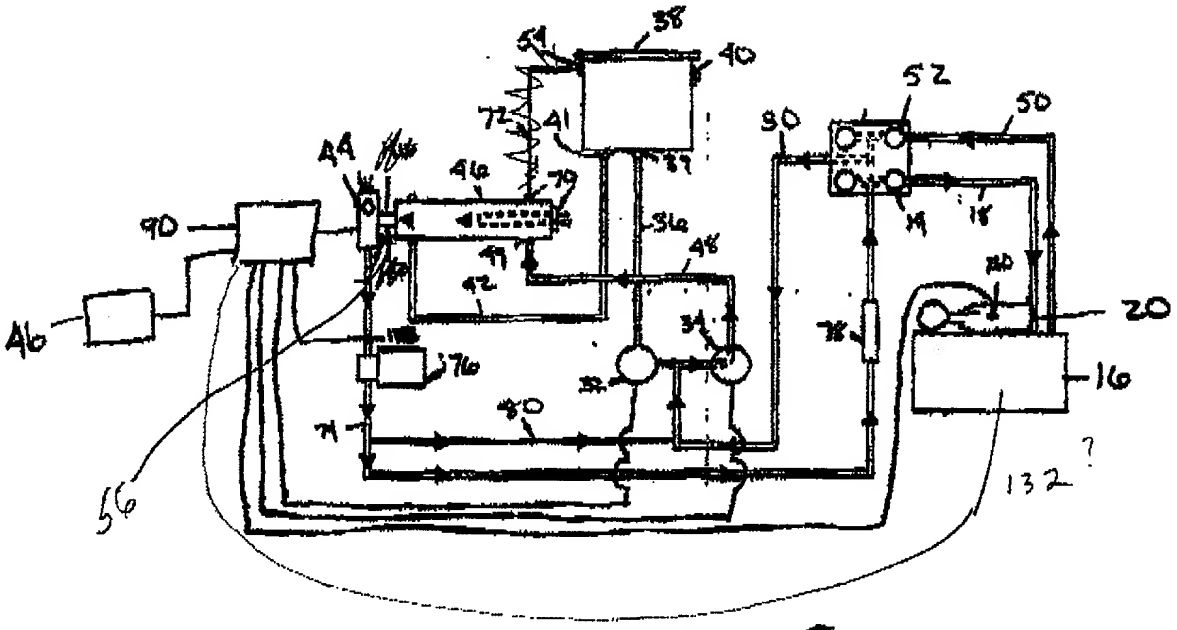


Figure 6

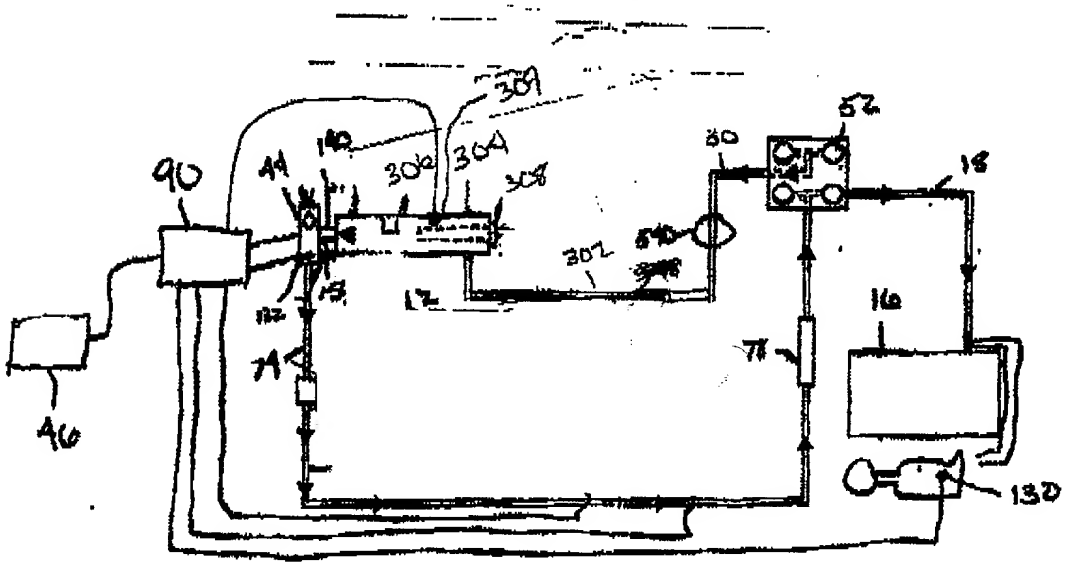
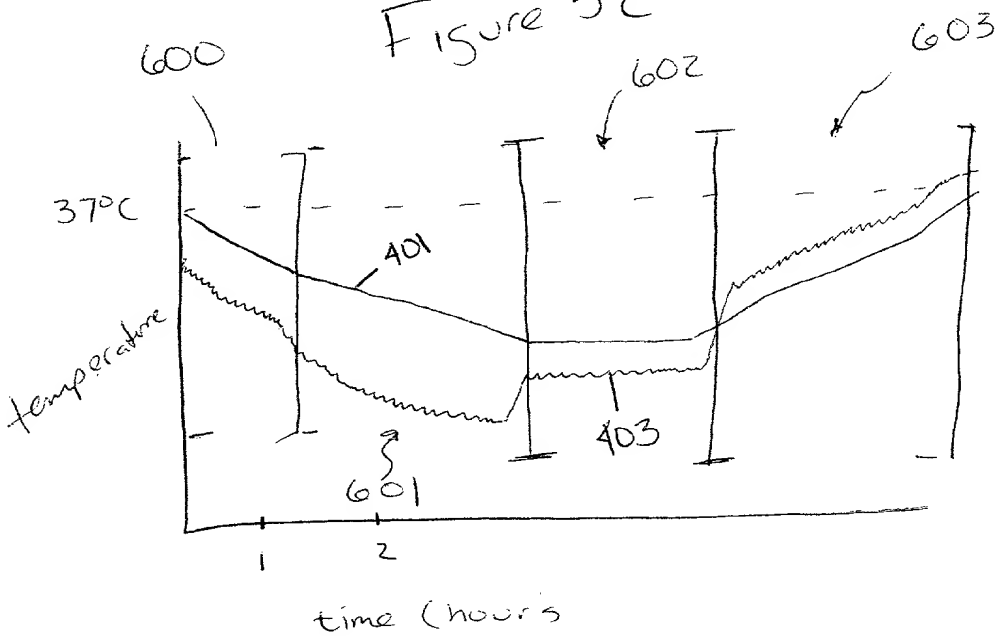


Figure 5C



Please type a plus sign inside this box ⊞ PTO/SB/01 (12/97) Approved for use through 09/30/00, OMB 0651-0032

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

Attorney Docket Number	01978.0229
First Named Inventor	Thomas P. Stewart et al.
COMPLETE IF KNOWN	
Application Number	
Filing Date	June 26, 2000
Group Art Unit	
Examiner Name	

■ Declaration Submitted with Initial Filing **OR** ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16(e)) required)

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

AUTOMATIC PATIENT CONTROL DEVICE

(Title of the Invention)

the specification of which
■ is attached hereto
OR

☐ was filed on (MM/DD/YYYY) [ ] as United States Application Number or PCT International Application Number [ ] and was amended on (MM/DD/YYYY) [ ] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application (Numbers)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	**Filing Date (MM/DD/YYYY)**	
		☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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DECLARATION – Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number *(if applicable)*

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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OR
■ Registered practitioner's name/registration number listed below

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Name	Registration Number	Name	Registration Number
Kevin D. McCarthy	40,041	R. Kent Roberts	40,786
Martin G. Linihan	24,926	Michael F. Scalise	34,920
Ranjana Kadle	35,278	Daniel C. Oliverio	33,435
David L. Principe	39,336	Edwin T. Bean, Jr.	16,639

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Thomas P.	Stewart

Inventor's Signature	Thomas P. Stewart					6/21/2000 **Date**	
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■ Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

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DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet Page 3 of 3

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
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Inventor's Signature	Hermann K. Pohl					6/22/00 **Date**	
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Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])			Family Name or Surname				
Inventor's Signature						**Date**	
Residence: City		**State**		**Country**		**Citizenship**	
Post Office Address							
Post Office Address							
City		**State**		**ZIP**		**Country**	

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])			Family Name or Surname				
Inventor's Signature						**Date**	
Residence: City		**State**		**Country**		**Citizenship**	
Post Office Address							
Post Office Address							
City		**State**		**ZIP**		**Country**	